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Attitudes of pregnant women towards participation in perinatal epidemiological research

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Summary

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We assessed attitudes of a multi-ethnic sample of pregnant women in regard to participation in five data collection procedures planned for use in the National Children's Study. A cross-sectional survey was conducted in nine prenatal clinics in Kent County, Michigan between April and October 2006. Women were approached in clinic waiting rooms at the time of their first prenatal visit and 311 (91.0%) participated. Women were asked about their willingness to participate, and the smallest amount of compensation required for participation in a 45-min in-person interview, a 15-min telephone interview, maternal and infant medical record abstraction, and an infant physical examination.

Percentages for willingness to participate were highest for telephone interview (83%), followed by in-person interview (60%), infant examination (57%), and maternal (56%) and infant medical records (54%). About 34–48% of women reported that no compensation would be required for participation by data procedure. Some women reported unwillingness to participate in telephone (9%) or personal (17%) interview, record abstraction (34%) or infant examination (26%), even with compensation. Education greater than high school was associated with increased odds of refusal for infant physical examination, adjusted odds ratio 2.44 [95% confidence interval 1.41, 4.23]. In conclusion, 9–34% of pregnant women, depending on procedure, stated they would not participate in non-invasive research procedures such as medical record abstraction and infant examination, even with compensation. Resistance to these research procedures was especially noted among more highly educated women. Planning for the National Children's Study will have to address potential resistance to research among pregnant women.

Keywords: *pilot*, *National Children's Study*, *refusal rate*, *maternal education*.

Introduction

High participation in all components of data collection protocols in epidemiological studies is important for valid study inferences.[1] Understanding both the feasibility of agreement to participate in data procedures and the role of compensation for participation among different populations may improve study planning, leading to optimal recruitment and retention methods. Pregnant women may have attitudes towards research participation that differ from other populations, possibly due to their health status and/or interest in learning about pregnancy.[2]

While substantial literature exists on hypothetical attitudes towards participation in various types of

research studies,[2–11] few studies have focused on observational research during pregnancy and at birth.[2,9,10] The literature is particularly limited for attitudes concerning willingness to participate in observational research among currently pregnant women. The one study we identified reported only general attitudes of pregnant women towards future prenatal research.[10]

In the light of the paucity of information on attitudes of pregnant women towards participation in observational research, we conducted a cross-sectional survey of attitudes of pregnant women in a multi-ethnic sample in Kent County, Michigan (MI). We assessed attitudes towards participation in five hypothetical data collection procedures planned for use in the National Children's Study (NCS) and the desired compensation for participation in each procedure. We also examined maternal factors associated with unwillingness to participate by data procedure.

Methods

Michigan Alliance for the National Children's Study-Pilot Study

The NCS will examine a variety of social, psychological, environmental and biological exposures in relation to child health and development.[12] Women will be recruited pre-conceptionally and during pregnancy and 100 000 children will be followed until 21 years of age. The Michigan Alliance for the National Children's Study (MANCS) was formed in 2002 to promote planning efforts for the NCS in MI.[13] Recognising the complexity of performing research in pregnant women, MANCS conducted a pilot study to examine attitudes of pregnant women and their health care providers to participation in procedures likely to be used in the NCS. From April–October 2006, in-person interviews of pregnant women were conducted and surveys were distributed to staff in prenatal care clinics and delivery rooms in Kent County.[14] The study was approved by the Institutional Review Boards of Michigan State University and three hospitals with labour and delivery services in the county.

Study population

Using data from the Kent County Health Department, 10 prenatal care clinics were sampled based on estimates of the annual number of prenatal patients and the racial/ethnic composition of the population. Selected practices included private, Medicaid/Medicare and bilingual (English/Spanish) clinics, as well as one midwifery clinic. Nine clinics allowed the interviewing of pregnant women.

Eligible women were pregnant, aged 18–50 years, making their first prenatal visit, and proficient in English or Spanish. Women at the clinic for their first prenatal visit received a study brochure at check-in, which included a description of the NCS and purpose of the pilot study. Interviewers approached women with a study brochure in clinic waiting rooms, determined eligibility and described the study. During enrolment, we missed 94 new patients because an interviewer was unavailable. We were unable to determine eligibility for these missed women. Among 374 women approached, 32 (8.0%) were found to be ineligible (20 were minors; 10 had a language barrier; 2 were not pregnant). Of the remaining 342 eligible women approached, 311 (91%) participated.

Data collection

Interviewers obtained written informed consent and conducted 15–20 min in-person interviews in English or Spanish either before or after appointments. Interviewers described the NCS and pilot study to eligible women. This included an explanation of how the NCS would involve many data collection procedures and that the purpose of the pilot study was to determine willingness to participate in specific parts, so if women were more resistant to a particular procedure, planning efforts for the NCS could be adjusted accordingly. (*The complete survey is available from the corresponding author).*

Attitudes towards hypothetical participation and compensation for planned procedures were assessed, including: (1) 45 min in-person interview during a prenatal care clinic visit; (2) 15 min telephone interview during pregnancy; (3) maternal medical record abstraction; (4) infant medical record abstraction; (5) infant physical examination; (6) maternal blood collection; (7) cord blood collection; (8) placenta collection; and (9) biological specimen storage. The first five procedures are the focus of this paper. Attitudes towards collection of biological specimens will be reported in a subsequent manuscript.

Women were first asked their willingness to participate in each procedure (yes, no, it depends). Second, women were asked the smallest amount of monetary compensation they would require to participate in each

procedure (no compensation required for participation, any dollar amount volunteered, or would not participate for any compensation). Third, women were asked to pick their top choice out of four compensation types (gift cards, free supplies/toys, college fund/savings bond and money). Maternal factors assessed included race/ethnicity, age, education, annual family income, relationship status, parity and gestational week (maternally estimated trimester only if week not known). Women completing the interview received a $10 gift card.

Study variables

We created categorical variables for willingness to participate when compensation attitudes were assessed (would participate if compensated, would participate for no compensation, would not participate for any compensation) and for lowest reported compensation amount by procedure ($0, $1–10, $11–20, $21–49, ≥$50). We created binary variables for unwillingness to participate by procedure (would not participate for any compensation, would participate for no/some compensation) for use in logistic regression analyses. Categorical variables were created for race/ethnicity, age, education for women ≥19 years of age and annual family income. Binary variables were used to describe relationship status (married: yes, no), parity (primiparous: yes, no) and trimester (first: yes, no).

Analysis

Frequencies and percentages (and means where appropriate) were calculated for attitudes and maternal factors. Logistic regression was used to examine factors associated with unwillingness to participate (would not participate for any compensation; reference = would participate) by procedure. We evaluated several factors together (race/ethnicity, age, education, income, marital status, parity and trimester) to determine the independent associations with unwillingness to participate in each procedure. Adjusted results include all maternal factors evaluated as potential confounders with some exceptions due to high correlation between covariates and/or lack of precision (see Table 5).

We used PROC GENMOD for logistic regression models to account for clustering by clinic and calculated odds ratios (ORs) and 95% confidence intervals [CI]. SAS version 9.1.3 was used for all analyses. *P*-values <0.05 indicated statistical significance.

Results

Table 1 displays participant characteristics. Women ranged in age from 18 to 41 years and close to half reported a family income <$25 000. Most women were interviewed in English (88%) and about 6% reported they were aware of the NCS.

The percentage of women that agreed to hypothetical participation was highest for telephone interview and lowest for maternal or infant medical record review (Table 2). For women who said 'it depends', the percentage was highest for infant physical examination and lowest for telephone interview (Table 2). Slightly more than half would agree to participate in both in-person and telephone interview (53%), and exactly one-half would participate in both maternal and infant medical record review. Just 70 women (23%) would

Table 1. Characteristics of pregnant women, MANCS Pilot Study ($n = 311$)[a]

	n (%)
Maternal race	
Non-Hispanic White	180 (59)
Non-Hispanic Black	51 (17)
Hispanic	61 (20)
Non-Hispanic other	14 (4)
Maternal age (years)	
<25	109 (35)
25–29	107 (35)
30–34	67 (22)
≥35	26 (8)
Annual family income (dollars)	
<25 000	137 (45)
25–49 999	73 (24)
≥50 000	96 (31)
Education (among women ≥19)	
< High school	63 (21)
High school	52 (18)
Some college	87 (29)
Bachelor's or higher	93 (32)
Married	159 (52)
Primiparous	126 (41)
First trimester	245 (79)

[a]Frequencies and percentages exclude missing by characteristic: race/ethnicity ($n = 5$), age ($n = 2$), income ($n = 5$), education ($n = 2$), married ($n = 4$).

MANCS, The Michigan Alliance for the National Children's Study.

Table 2. Willingness to participate by planned data procedure among pregnant women, MANCS Pilot Study

	Willingness to participate[a]		
	Yes *n* (%)	No *n* (%)	It depends *n* (%)
45 min in-person interview	179 (60)	68 (23)	53 (18)
15 min telephone interview	256 (83)	37 (12)	16 (5)
Maternal medical record abstraction	164 (56)	88 (30)	42 (14)
Infant medical record abstraction	157 (54)	84 (29)	49 (17)
Infant physical examination	167 (57)	64 (22)	62 (21)

[a]Frequencies and percentages exclude missing by procedure: in-person interview ($n = 11$), telephone interview ($n = 2$), maternal medical records ($n = 17$), infant medical records ($n = 21$), infant examination ($n = 18$).
MANCS, The Michigan Alliance for the National Children's Study.

agree to all five procedures, while 12 women (4%) said they would refuse to participate in all procedures.

Table 3 displays willingness to participate when compensation attitudes were assessed. Willingness increased when compensation was offered; however, some women reported they would not participate even with compensation.

Table 4 shows monetary compensation attitudes by data procedure for women who reported they would be willing to participate. The mean amount of monetary compensation was highest for infant examination and lowest for telephone interview. About 52–66% of women (by procedure) reported they would require compensation for participation. We also asked women to pick their top choice out of four types of compensation. A college fund was preferred by most women (54%), followed by gift cards (24%), money (14%) and free supplies/toys (8%).

We examined factors associated with unwillingness to participate even with compensation by data procedure (Table 5). In unadjusted models (data not shown),

Table 3. Willingness to participate when compensation attitudes were assessed among pregnant women, MANCS Pilot Study[a]

	Would participate if compensated *n*(%)	Would participate for no compensation *n* (%)	Would not participate for any compensation *n* (%)
45 min in-person interview	154 (54)	80 (28)	49 (17)
15 min telephone interview	139 (48)	126 (43)	27 (9)
Medical record abstraction[b]	97 (35)	88 (32)	93 (34)
Infant physical examination	109 (40)	91 (34)	70 (26)

[a]Frequencies and percentages exclude missing by data procedure: in-person interview ($n = 28$), telephone interview ($n = 19$), medical records ($n = 33$), infant examination ($n = 41$).
[b]For compensation questions, maternal medical records and infant medical records were not assessed separately.
MANCS, The Michigan Alliance for the National Children's Study.

Table 4. Compensation attitudes by planned data procedure among pregnant women who agreed to hypothetical participation, MANCS Pilot Study[a]

	Lowest amount of monetary compensation					
	Mean (SE)[b]	$0 *n* (%)	$1–10 *n* (%)	$11–20 *n* (%)	$21–49 *n* (%)	≥$50 *n* (%)
45 min in-person interview	37 (2.6)	80 (34)	30 (13)	47 (20)	28 (12)	49 (21)
15 min telephone interview	17 (2.2)	126 (48)	78 (29)	40 (15)	15 (6)	6 (2)
Medical record abstraction	45 (7.7)	88 (48)	29 (16)	20 (11)	17 (9)	31 (17)
Infant physical examination	57 (10.4)	91 (46)	17 (8)	27 (14)	20 (10)	45 (23)

[a]Frequencies and percentages exclude missing and women who would not participate for any amount of compensation by procedure.
[b]Means exclude women who reported $0 by procedure and 1 woman who reported $5000 for each procedure (SE, standard error).
MANCS, The Michigan Alliance for the National Children's Study.

Table 5. Adjusted odds ratios for unwillingness to participate in planned data procedures even if offered compensation, MANCS Pilot Study[a]

	45 min in-person interview OR [95% CI][b]	15 min telephone interview OR [95% CI][b]	Medical record abstraction OR [95% CI][b]	Infant physical examination OR [95% CI][b]
Race/ethnicity[c]				
NH White	1.00 Reference	1.00 Reference	1.00 Reference	1.00 Reference
NH Black	1.78 [0.42, 7.45]	2.36 [0.81, 6.92]	1.83 [0.68, 4.96]	1.03 [0.36, 3.01]
Hispanic	1.95 [0.70, 5.40]	2.07 [0.61, 7.01]	1.78 [0.93, 3.39]	1.58 [0.55, 4.56]
Maternal age				
<25 years	**1.51 [1.18, 1.93]**	1.44 [0.69, 3.03]	1.01 [0.60, 1.70]	0.87 [0.49, 1.53]
≥25 years	1.00 Reference	1.00 Reference	1.00 Reference	1.00 Reference
Education[d]				
<High school	1.00 Reference	1.00 Reference	1.00 Reference	1.00 Reference
High school	0.71 [0.26, 1.92]	1.45 [0.87, 2.40]	1.45 [0.68, 3.08]	0.95 [0.38, 2.37]
>High school	1.03 [0.34, 3.16]	1.11 [0.51, 2.42]	2.23 [0.97, 5.15]	**2.44 [1.41, 4.23]**
Annual income				
<$25 000	1.00 Reference	1.00 Reference	1.00 Reference	1.00 Reference
≥$25 000	0.63 [0.24, 1.61]	0.80 [0.22, 2.97]	1.15 [0.45, 2.96]	0.73 [0.29, 1.82]
Marital status				
Married	1.85 [0.65, 5.27]	0.91 [0.42, 1.98]	1.10 [0.63, 1.90]	1.16 [0.74, 1.80]
Not married	1.00 Reference	1.00 Reference	1.00 Reference	1.00 Reference
Primiparous				
Yes	1.17 [0.53, 2.57]	1.14 [0.63, 2.04]	1.17 [0.61, 2.22]	1.03 [0.55, 1.92]
No	1.00 Reference	1.00 Reference	1.00 Reference	1.00 Reference

[a]Table excludes missing data by procedure. ORs statistically significant at $\alpha \leq 0.05$ level are in bold print.
[b]Adjusted for age, education, marital status, parity and trimester (where appropriate); models where education is the main factor of interest are also adjusted for race/ethnicity.
[c]Excludes NH other ($n = 14$).
[d]Among participants ≥19 years of age.
MANCS, The Michigan Alliance for the National Children's Study; NH, non-Hispanic.

women of younger age (<25 years) were less likely to report they would refuse to participate in an infant examination (OR 0.55 [95% CI 0.32, 0.94]). Women of higher education (> high school) were more likely to report they would refuse to participate in record abstraction (OR 2.46 [95% CI 1.53, 3.94]) and infant examination (OR 2.72 [95% CI 1.73, 4.26]), as were married women for record abstraction (OR 1.45 [95% CI 1.03, 2.04]) and infant examination (OR 1.72 [95% CI 1.11, 2.67]). After adjustment, only the positive association between higher education and refusal for infant examination remained significant. In addition, in adjusted analyses, younger maternal age was associated with an increased likelihood of refusal for personal interview (Table 5).

Discussion

This cross-sectional survey provides data on pregnant women's attitudes towards hypothetical research participation and desired compensation. We found that a majority of pregnant women (54–83%, depending on procedure) would participate in non-invasive research procedures commonly used in epidemiological studies, such as interviews, record abstraction and examinations. Moreover, 34–48% of women who would participate would do so without compensation (depending on procedure). However, 9–34% of women would refuse to participate in such procedures, even with compensation. Resistance was highest for medical records and infant physical examinations. We found evidence for increased resistance to those procedures among women with higher education. Younger women were more likely to resist longer in-person interviews.

The attitudes of pregnant women towards hypothetical participation in observational research during pregnancy and at birth have largely been unexplored. Jorgensen reported that 59% of Danish pregnant women who accepted or declined an alpha-fetoprotein test would support continued prenatal research.[10]

Daniels and colleagues found that the majority of postpartum women who had recently participated in a cohort study of pregnancy reported that they felt comfortable with all study procedures and 80% said they would be willing to participate in a future study of pregnancy.[2]

In our study of hypothetical attitudes, we were interested in associations between maternal factors and unwillingness to participate, even with compensation. Most maternal factors were not significantly associated with resistance to participation in the five data procedures. We did find, however, that higher education (>high school) was associated with increased resistance to an infant physical examination and possibly to record abstraction. Younger age was associated with increased resistance to in-person interviews. Some studies of attitudes to participation in hypothetical research situations have found differences by education,[2] while others have not.[4,9] Daniels and colleagues examined attitudes of mothers towards participation of their children in future research activities and found some evidence that women of higher education were more resistant, although results were very imprecise.[2]

To our knowledge, data on pregnant women's attitudes towards monetary compensation for hypothetical involvement in specific research procedures have not been reported previously. We found that about 34–48% of pregnant women would not require monetary compensation for participation. This finding fits with previous studies that have found contribution to science and learning about pregnancy to be main motivators for actual participation in studies during pregnancy.[2,15]

Depending on procedure, monetary suggestions were fairly similar to those used in practice for a majority of women (e.g. close to 80% of women suggested $0–10 for a short telephone interview[16]); however, about 20% of women asked for $50 or more for participation in personal interviews, medical record review and infant examinations. We also found that when asked to select their top choice of compensation, more women chose a college fund/savings bond or gift cards, rather than money. Although published reports provide important data on motivating factors for actual participation in studies conducted during pregnancy,[2,15,17] these studies exclude women who did not participate. Our results can inform discussions on the appropriate compensation amounts/types to be used for observational research among pregnant women.

Strengths of our study include: (1) prenatal care clinics sampled to represent a cross-section of the county population and to include clinics serving a variety of ethnic and socio-economic strata; (2) participation of nine out of ten clinics sampled; (3) >90% participation rate for eligible pregnant women approached; and (4) inclusion of a high proportion of both non-Hispanic Black and Hispanic women, improving the generalisability of study results to other general populations of pregnant women.

Several study limitations must be noted. Because our study is not population-based, the results may not be generalisable to all pregnant women who received services at prenatal care clinics in Kent County during the enrolment period. We did, however, compare the demographics of our sample to vital statistics data for 2006 livebirths in the county and percentages were similar for most maternal demographics, which suggests our sample is fairly representative.[18] Second, since our study was conducted in clinics, women's attitudes may have been more positive due to perceived support of the study by their health care providers, although our recruitment methods parallel the way in which some women will be recruited for the NCS. Third, we assessed attitudes for hypothetical situations. Attitudes may change over time and also may not reflect actual behaviour.[19,20] Another limitation is that we did not collect information on why women reported that they were unsure or unwilling to participate in the research procedures.

Our key finding – that while most women are open to non-invasive medical research in pregnancy, a minority are quite resistant – is an important message for pregnancy research in general, and for the NCS in particular. It is reasonable to expect that when an actual study is presented to pregnant women, its rationale explained in detail, and its commitment to security of data affirmed, participation rates may be higher than found in our survey. Confidentiality of research information is especially important to address, in light of the high levels of resistance we encountered to medical record abstraction. The NCS also plans substantial community engagement efforts in its study locations that should encourage participation. Our results indicate that such efforts will be very important if enrolment in the NCS is to be optimised.

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